Exhibit #9 510(k) Summary

MAY 2 8 2013

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K123801

1. Prepared Date: March 01, 2013

2. Sponsor

   Shenzhen Kingyield Technology Co., Ltd
   Bldg C, Fuhai Industrial Zone, Fuhai Road, Fuyong Town,
   Baoan, Shenzhen, 518103, China

   Establishment Registration Number: 3007420856

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3. Submission Correspondent
   Ms. Diana Hong & Mr. Lee Fu
   Mid-Link Consulting Co., Ltd
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   Fax: 240-238-7587
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4. Proposed Device Identification

   Proposed Device Name: Finger Pulse Oximeter
   Proposed Device Model: PM601
   Device Common Name: Pulse Oximeter
   Classification Name: Oximeter

   Classification: 2
   Product Code: DQA

Regulation Number: 21 CFR 870.2700
Review Panel: Anesthesiology

Indications for Use:
PM601 Finger pulse oximeter is intended for spot-checking oxygen saturation in blood (SpO2) and pulse rate. The pulse oximeter is used on adults at hospital, clinics, and/or home. Not for continuously monitoring.

5. Predicate Device Identification

510(k) Number: k093757
Product Name: MD300C1 Fingertip pulse oximeter
Manufacturer: Beijing Choice Electronic Technology Co., Ltd

6. Device Description

The proposed device, Finger Pulse Oximeters PM601 is a fingertip device, which can display % SpO2, pulse rate value and pulse strength. It is based on digital blood oxygen.

Power consumption of the proposed device is low and the two originally-equipped AAA alkaline batteries can be operated continuously for 24 hours. It will automatically turned off when no signal is detected for more than 8 seconds. And low voltage warning will be displayed and battery symbol flash when battery voltage is low.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1:2005 + CORR.1 (2006) + CORR.2 (2007), Medical electrical equipment – Part 1: General requirements for basic safety, and essential performance.
IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
ISO 80601-2-61:2011, Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.
ISO 9919: 2005, Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
ISO 10993-5: 2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity.
ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

8. Clinical Trial Conclusion

The clinical trial was performed according to Annex EE.2 Procedure for invasive laboratory testing of ISO9919:2005 Medical electrical equipment— Particular requirements for the basic safety and essential performance of pulse oximeter equipment for the medical use on ten healthy volunteers.

It can be determined from the result of the clinical study that the accuracy Arms of the proposed device is smaller than 3%.

9. Substantially Equivalent

Table III-1 Substantially Equivalent Comparison

ITEM	Proposed Device Finger Pulse Oximeter PM601	Predicate Device MD300C1 Fingertip pulse oximeter (k093757)
Product Code	DQA	Same
Regulation No.	21 CFR 870.2700	Same
Class	2	Same
Intended Use	PM601 Finger pulse oximeter is intended for spot-checking oxygen saturation in blood (SpO2) and pulse rate. The pulse oximeter is used on adults at hospital, clinics, and/or home. Not for continuously monitoring.	Similar
SpO_2 measurement range	70%-100%	Same
SpO_2 accuracy	70%~100%, ±3%	Same
PR measurement range	30-199 bpm	Similar
PR accuracy	±2 bpm or ±2% MAX	Same
Patient Contact Material	Silicone	Same
Electrical Safety	Comply with IEC 60601-1	Same
EMC	Comply with IEC 60601-1-2	Same

The proposed device has the same classification information, similar intended use, same design principle, similar specifications and same safety performance as the predicate device. The difference in intended use and PR measurement range are discussed in the 510(k) submission documents, it is concluded that these differences will not affect the effectiveness and safety of the proposed device. And the results of bench tests and clinical trial have been conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device.

The proposed device, Finger Pulse Oximeter PM601, is determined to be Substantially Equivalent (SE) to the predicate device, MD300C1 Fingertip pulse oximeter (k093757), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 28, 2013

Shenzhen Kingyield Technology Company, Limited
C/O Ms. Diana Hong
General Manager
MID-Link Consulting Company, Limited
P.O. Box 237-023
Shanghai
China 200237

Re: K123801
Trade/Device Name: Finger Pulse Oximeter PM601
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: April 17, 2013
Received: April 29, 2013

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

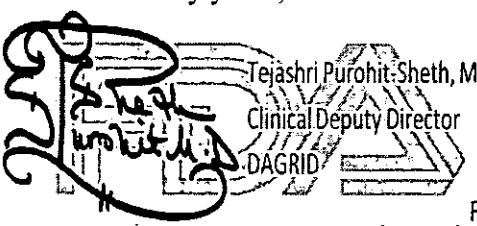
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR
Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section II Indications for Use

510(k) Number: K123801
Device Name: Finger Pulse Oximeter PM601

Indications for Use:

PM601 Finger pulse oximeter is intended for spot-checking oxygen saturation in blood (SpO2) and pulse rate. The pulse oximeter is used on adults at hospital, clinics, and/or home. Not for continuously monitoring.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neel J. Patel -S
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123801